# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt. 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

Judge Rya Zobel

All Cases Identified In Dkt. Nos. 1401, 1471, 1472, & 1473.

PLAINTIFFS' STEERING COMMITTEE'S RULE 56(d) RESPONSE TO LIBERTY INDUSTRIES INC. OMNIBUS MOTION FOR SUMMARY JUDGMENT IN CASES FILED BY PLAINTIFFS INJECTED IN INDIANA.

The Plaintiffs' Steering Committee on behalf of the plaintiffs identified in the above-captioned cases submits this Rule 56(d) response to Liberty Industries, Inc.'s ("Liberty") Rule 56 Motion for Summary Judgment In Cases Filed By Plaintiffs Injected in Indiana (Dkt. No. 1401, 1472 and 1473, collectively the "Liberty Motion for Summary Judgment"). The Liberty Motion for Summary Judgment requests summary dismissal of all the above-identified individual lawsuits.

Liberty supports its Motion for Summary Judgment by relying upon the affidavit of Jeffrey Erickson, Liberty's Engineering Manager who was allegedly the person principally responsible for the design and construction of "clean" rooms at the New England Compounding Center's ("NECC") Framingham, Massachusetts facility. Plaintiffs have not been afforded the opportunity to depose this witness, nor have Plaintiffs been allowed to complete basic factual discovery. Expert discovery has not yet commenced and will be necessary once adequate fact discovery has occurred. Therefore, the PSC files this Rule 56(d) response and the contemporaneously filed declaration of Marc Lipton (the "Lipton Decl.") requesting that the Court deny the Liberty Motion for Summary Judgment and permit the PSC to complete discovery, including expert discovery, prior to addressing the merits of the Liberty Motion for Summary Judgment.

### I. Introduction and Background

The Motion for Summary Judgment is untimely and Plaintiffs should be permitted to conduct meaningful discovery before responding to it.

This litigation arises from a widespread outbreak of fungal meningitis affecting victims in at least 20 states. According to the CDC, to date, more than 750 people have been diagnosed with fungal meningitis, fungal infections and/or abscesses. More than 60 people have died.

The fungal infections were caused by a contaminated prescription medication known as  $\{004663/12496/00337194.DOCX / Ver.2\}2$ 

methylprednisolone acetate ("MPA"). Pain clinics and hospitals purchased the contaminated MPA from a compounding pharmacy known as New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") located in Framingham, Massachusetts and ultimately injected patients with this tainted pharmaceutical.

Liberty designed and constructed three clean rooms where NECC compounded the tainted MPA that was ultimately injected into patients. The Amended Master Complaint alleges a single cause of action for negligence and gross negligence against Liberty because it failed to exercise reasonable care in one or more of the following ways:

- a. by failing to properly design and install the 2006 and 2008 Cleanroom ceiling grids, ceiling panels, light fixtures, and HEPA filtration modules;
- b. by failing to properly design and install the 2006 and 2008 Cleanroom fire suppression system;
- c. by failing to use proper materials in the construction of the ceiling of the Cleanrooms;
- d. by failing to properly survey existing Cleanrooms and the facility as a whole to properly assess the risks associated with construction of subsequent Cleanrooms;
- e. by failing to install a hard cap/hard ceiling over the ceiling of each Cleanroom to protect from contamination, despite Liberty's actual and/or constructive knowledge that the areas between the ceilings of the 2006 and 2008 Cleanrooms were prone to excessive contamination and water damage;
- f. by prematurely certifying the 2006 and 2008 Cleanrooms;
- g. by disrupting or otherwise breaching the cleanliness of the Cleanrooms through the installation of faulty ceiling grids, improper materials, and the conduct of subsequent work to each Cleanroom, resulting in or contributing to their contamination;
- h. by failing to take reasonable steps to properly certify the Cleanrooms to ensure their cleanliness as required for their anticipated use.<sup>1</sup>

In short, the PSC alleges that Liberty proceeded with the design and construction projects of the clean rooms without adequate environmental analysis, utilized subpar designs, issued premature certifications, failed to properly seal the rooms, and installed them defectively,

<sup>1</sup> Dkt. No. 545 at ¶ 213.

contributing to the contamination of the cleanrooms from outside particles. This caused the outbreak of fungal meningitis and other injuries in patients in 20 states. The limited discovery the PSC has been able to obtain thus far against Liberty supports these allegations.

For example, email correspondence between Liberty and NECC show that in March of 2008, Liberty was onsite at NECC's building in Framingham to fix ceiling tiles which were not properly seated in the ceiling grid.<sup>2</sup> Jeff Erickson of Liberty wrote to Steve Higgins at NECC that he fixed five ceiling tiles, but "while I was working on the last two (2) tiles, I heard ceiling tile clips popping off the T-grid. Four (4) new additional tiles were now popping up near the Cart Pass Thru." He goes on to say, "I identified what was happening because of the present air pressures in the cleanroom." The subsequent discussion shows no indication that Liberty considers that the T-grid was defectively designed and installed or that air pressure problems exist which cannot be remedied by the HVAC system.<sup>5</sup>

NECC/Ameridose replies to Liberty in frustration that, "I would think the people who routinely design cleanrooms would 1) know that 0.2in of water is a high pressure which might lead to ceiling tiles and doors being popped and 2) know what the pressurization scheme should be for a cleanroom without me having to define it...that is the expertise we are paying for."

Additional documents show that in November 2005, after certification of the first cleanroom, Liberty contacted its wall system supplier, Porta-King, to seek reimbursement for "reject-able" products that were used in the installation of the cleanroom because "the commitment to get a cleanroom up and running in a given time period sometimes forces us to

<sup>2</sup> Lipton Decl., at ¶ 2, Ex. 1.

<sup>3</sup> Lipton Decl. at ¶ 2, Ex. 1.

<sup>4</sup> *Id*.

<sup>5</sup> *Id*.

<sup>6</sup> *Id*.

work with the material delivered."<sup>7</sup> Merely seeking reimbursement for "reject-able materials" after installing them hardly creates confidence in the integrity of a cleanroom that is intended to allow the safe production of compounded pharmaceuticals.

Also, Liberty represented that it would provide NECC with an ISO 6 cleanroom "certified as built, prior to installation of customer supplied equipment in strict accordance with ISO Standard 14644-1." Liberty failed in performing this critical obligation. While the 2006 Cleanroom was still being built on July 12, 2006, Liberty authorized its certification "at rest," not "as built" as was promised in its November 21, 2005 proposal to NECC. "At rest" is a more stringent condition than "as built," "where installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present." Most importantly, under the ISO Standards, "as built" certification requires more testing, whereas "at rest" does not. Thus, Liberty knowingly used the wrong certification method, when the cleanroom had not yet reached the "as built" condition, and in doing so avoided any future obligation for certification as required by ISO14644-4 (Section 3.1) and as promised.

Further, on July 10, 2006, just two days prior to the scheduled certification, Liberty conveyed to NECC that it felt as though "[certification] may be premature for the following reasons" and went on to identify at least four key issues that remained to be installed or completed before a proper certification should have been sought. 11 Despite acknowledging these defects, Liberty scheduled the third party certification testing anyway, stating that "[i]f the

<sup>7</sup> *Id.* at ¶ 3 and Ex. 2.

<sup>8</sup> *Id*.

<sup>9</sup> *Id.* at ¶ 4 and Ex. 3.

<sup>10</sup> See id. at ¶ 4 and Ex. 4 at ISO 1466-1:1999(E)(2.4.2).

<sup>11</sup> *Id*. at ¶ 6 and Ex. 5.

certification tests are passed, we will consider the project certification complete." <sup>12</sup> ISO 14644-4 does not allow these types of defects to remain when performing "as built," let alone "at rest" certification of a cleanroom.

Moreover, during the post-outbreak inspection of the Liberty cleanrooms it was observed that the ceiling system of the cleanroom was improperly designed and installed, consistent with Liberty's observations in the March 2008 email discussed above. <sup>13</sup> Large gaps were present between the light fixtures and the ceiling grid and similar large gaps were present between some of the HEPA filters and the ceiling grid. <sup>14</sup>

In the case of the main cleanroom area of the 2006 Cleanroom, gaps between the grid and some of the filters and light fixtures were large enough to push a pencil through the spaces. <sup>15</sup> In particular, one filter unit was observed to have a gap larger than 1/4" wide at its widest point, running the length of the HEPA filter on two sides, between its perimeter and the ceiling grid. <sup>16</sup> When viewed from above the ceiling, one could look directly down into the cleanroom below. <sup>17</sup>

These gaps would have allowed contaminants to "rain" down into the cleanroom through both open unrestricted airflow and gravitational settling. Of particular concern would be the large amount of contaminants that could enter through such large gaps during a period of high pressure in the attic space. Worst of all, the largest observed gap was directly above an area in which it is believed that compounding of contaminated drugs was performed and significant debris was observed adjacent to the gap, on top of the HEPA filter and adjacent lights and ceiling

<sup>12</sup> *Id*.

<sup>13</sup> *Id.* at ¶ 7 and Ex. 6.

<sup>14</sup> Id.

<sup>15</sup> *Id*.

<sup>16</sup> *Id*.

<sup>17</sup> *Id*.

tiles. 18

These preceding facts are only some of the key facts uncovered so far in the limited discovery undertaken to date. Further written discovery, depositions, and expert discovery remains to be done. In September, the Court entered its "Order Regarding Common-Issue Discovery" establishing the timing of common discovery in this MDL. <sup>19</sup> Fact discovery remains open until June 15, 2015. Expert discovery will begin in July of 2015 and is not scheduled to end until October, 2015. The common issue dispositive motion deadline of August 14, 2015 is almost a full year *after* Liberty filed the present motion. <sup>20</sup>

Notwithstanding these facts and the procedural posture of this case, Liberty now moves this Court for the summary dismissal of almost 100 lawsuits brought as a result of this national tragedy. In support of its Motion, Liberty tendered an affidavit of Jeffrey Erickson, the engineer responsible for constructing the three cleanrooms at NECC.<sup>21</sup> This self-serving affidavit seeks dismissal principally on the following grounds:

- Liberty observed nothing wrong with the cleanrooms it designed and manufactured for NECC;<sup>22</sup>
- The NECC cleanrooms were certified compliant with relevant ISO standards;<sup>23</sup>
- NECC failed to maintain the cleanrooms designed and constructed by Liberty and Liberty had no knowledge of NECC's failure to maintain these cleanrooms.<sup>24</sup>

The Erickson Affidavit is meant to establish that Liberty did nothing wrong in its design and

19 Dkt. No. 1425 (hereinafter the "Common Discovery Order").

21 Dkt. No. 1472-2 at Page 3, ¶ 1.

22 Dkt. No. 1472-2 at P. 9, ¶ 18-21.

23 Dkt. No. 1472-2 at P.7, ¶ 12.

<sup>18</sup> Id.

<sup>20</sup> Dkt. No. 1425 at P. 5.

<sup>24</sup> Dkt. No. 1472-2 at P. 9-12, ¶¶ 22-24. These conclusions were principally based on Mr. Erickson's July 2014 inspection of the NECC facilities, an inspection that occurred almost two years after the relevant outbreak and almost 20 months following NECC's filing of its Chapter 11 petition.

construction of the cleanrooms where NECC compounded contaminated MPA and that NECC is the sole party responsible for the abysmal state of the Liberty cleanrooms. <sup>25</sup> Mr. Erikson admits that he observed roof work being done over the clean room areas, but offers nothing which addresses Liberty's analysis and decision to build cleanrooms in the NECC facility. However, Liberty provides no independent expert testimony or any outside testimony from any third party to support these allegations. <sup>26</sup> Instead, it relies solely on the affidavit of the one person responsible for the design and construction of those cleanrooms. In other words, the Liberty seek summary judgment on grounds of nothing more than that it, and it alone, believes it did nothing wrong.

### II. Legal Argument

a. RULE 56(D) IS INTENDED TO ALLOW A PARTY FACED WITH A PREMATURE MOTION FOR SUMMARY JUDGMENT TO OBTAIN DENIAL OF THAT MOTION PENDING AN OPPORTUNITY TO TAKE DISCOVERY

Fed. R. Civ. P. 56(d) states:

If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it...

"When properly invoked, Rule 56[d] allows a party opposing summary judgment additional time to conduct discovery on matters related to the motion."<sup>27</sup>

"Typically, a successful Rule 56(d) motion must: 1) be timely; 2) be authoritative; 3) show good cause for failure to discover the relevant facts earlier; 4) establish a plausible basis for believing that the specified facts probably exist, and 5) indicate how those facts will influence

26 See generally Dkt. No. 1472.

<sup>25</sup> See generally id.

<sup>27</sup> See *C.B. Trucking v. Waste Mgmt.*, 137 F.3d 41, 44 (1st Cir. 1998). ("[D]istrict courts should liberally grant Rule 56 continuances where the Rule's preconditions for relief have been satisfied." *Pina v. Children's Place*, 2014 U.S. App. LEXIS 1537 (1st Cir. 2014), citing *Simas v. First Citizens' Fed. Credit Union*, 170 F.3d 37, 46 (1st Cir. 1999).

the outcome of summary judgment."28

The First Circuit has held that when all five elements of a Rule 56(d) motion are satisfied, "a strong presumption arises in favor of relief...[and] unless the movant has been dilatory, or the court reasonably concludes that the motion is a stalling tactic or an exercise in futility, it should be treated liberally."<sup>29</sup>

In evaluating a Trial Rule 56(d) motion, general instruction can be found in the case of *Simas vs. First Citizen's Fed. Credit Union*, 170 F.3d 37 (1<sup>st</sup> Cir. 1999). There, the First Circuit reversed a district court ruling denying a motion under then, Rule 56(f) now, 56(d). The appellate court wrote:

Rule 56(f) proffer need not be presented in a form suitable for admission as evidence at trial, so long as it rises sufficiently above mere speculation. This is as it should be, for Rule 56(f) is best understood as a complement to other provisions contained in Rule 56, allowing the opposing party to explain why he is as of yet unable to file a full-fledged opposition, subject to the more harrowing evidentiary standard that governs under Rules 56(e) and 56(c). Thus, reliance on hearsay is not, per se, a dispositive defect under Rule 56(f).

Furthermore, the Rule 56(f) motion filed by Simas did not rely exclusively on the information provided by the unnamed source, but also on the personal knowledge counsel had gained in subsequent consultations with DeBarros' counsel, who confirmed that DeBarros feared retaliation were he to testify against Silva. The latter evidence would provide rational support for Simas' counsel's suspicion that the DeBarros testimony would prove damaging to Silva.

On the present record, therefore, Simas appears to have satisfied all five preconditions for obtaining a Rule 56(f) continuance. When all five requirements are satisfied . . . a strong presumption arises in favor of relief . . . [and the movant] should be treated liberally. Thus, since the district court never resolved the Rule 56(f) motion on the merits, we cannot affirm its summary judgment ruling on the alternative ground suggested by defendants. <sup>30</sup>

In short, when faced with a premature motion for summary judgment, Rule 56(d) is

<sup>28</sup> Simas, 170 F.3d at 45 n.4; see also Resolution Trust Corp. v. N. Bridge Assocs., Inc., 22 F.3d 1198, 1203 (1st Cir. 1994).

<sup>29</sup> Resolution Trust Corp. vs. Northbridge Assoc., 22 F.3d 1198, 1203 (1st Cir.1994).

<sup>30 &</sup>lt;u>Simas v. First Citizens' Fed. Credit Union</u>,170 F.3d 37, 46 (1st Cir. 1999) (internal citations and quotations omitted).

meant to provide a non-moving party with an opportunity to defer responding to a motion for summary judgment and give that party an opportunity to conduct additional discovery, when the non-moving party establishes a plausible basis for believing that facts exist that will support denial of the motion but the party has not yet had the opportunity to conduct discovery to create such an issue.<sup>31</sup>

Given that the Plaintiffs here have not had any opportunity to conduct meaningful discovery, and have not had the opportunity to conduct a single fact deposition and have meaningful expert discovery, the bar for satisfying Rule 56(d) is particularly low. Courts grant almost as a matter of course, Rule 56(d) requests when the nonmoving party has not had the opportunity to conduct discovery.<sup>32</sup>

# B. PLAINTIFFS HAVE DEMONSTRATED THE PRECONDITIONS FOR RULE 56(D) RELIEF ARE SATISFIED.

As indicated above, "a successful Rule 56(d) motion must: 1) be timely; 2) be authoritative; 3) show good cause for failure to discover the relevant facts earlier; 4) establish a plausible basis for believing that the specified facts probably exist; and 5) indicate how those facts will influence the outcome of summary judgment."

i. The Timeliness And Authoritativeness Of This Motion Cannot Reasonably Be Questioned.

This Rule 56(d) response clearly and unmistakably satisfies the requirements of timeliness. Typically, Rule 56(d) motions are only denied on grounds of untimeliness when

<sup>31</sup> See Simas, 170 F.3d at 46; Commonwealth Aluminum Corp. v. Markowitz, 164 F.R.D. 117 (D. Mass 1995) (granting Rule 56d motion for continuance when party presented evidence of a "a plausible basis for a belief that discoverable materials exist that would likely suffice to raise a genuine issue of material fact and, thus, defeat summary judgment.").

<sup>32</sup> See e.g., Wichita Falls Office Assocs. v. Banc One Corp., 978 F.2d 915, 919 n.4 (5th Cir. 1992) (holding that courts grant Rule 56(d) motions "almost as a matter of course unless the non-moving party has not diligently pursued discovery of the evidence."); see also Oahn Nguyen Chung v. Studentcity.com, Inc., Case No. 10-10943, 2013 U.S. Dist. LEXIS 173911, 4-5 (D. Mass. Dec. 12, 2013) (Zobel, J.) (granting Rule 56(d) relief when no discovery had occurred and noting that "[Rule 56(d)] is intended to safeguard against judges swinging the summary judgment axe too hastily.")

<sup>33</sup> Simas, 170 F.3d at 45 n.4; see also Resolution Trust Corp., 22 F.3d 1198 at 1203.

Plaintiffs' counsel have failed to diligently pursue discovery and the discovery period has lapsed or passed by the time a responding party filed a Rule 56(d) response.<sup>34</sup> In the present case, discovery has barely begun, let alone concluded. Under the Court's current scheduling order, common-issue discovery, which is the discovery Plaintiffs need to fully respond to Liberty's motion, remains open until June of next year.<sup>35</sup> Plaintiffs have not had a meaningful opportunity to obtain written discovery or take any depositions of relevant Liberty employees and agents, including the person submitting the affidavit Liberty uses to support its Motion for Summary Judgment. Further, Mr. Erickson's qualifications raise independent issues as to whether he is suited to be opining on sources of contamination. An expert will be needed to assess nearly anything Liberty and its employees state regarding sources of contamination and their likelihood to contaminate. Therefore, the timeliness of this Rule 56(d) response cannot reasonably be questioned.<sup>36</sup>

Furthermore, counsel for Plaintiffs submit a declaration explaining the basis for believing that additional facts exist for the resolution of the Motion for Summary Judgment.<sup>37</sup> Therefore, this Rule 56(d) is unquestionably authoritative.<sup>38</sup>

#### ii. Good Cause Exists For Failure To Discover Facts Earlier

Although this MDL has been pending for some time, Plaintiffs have not had a meaningful opportunity to conduct discovery against Liberty and obtain the necessary expert reports likely necessary to respond to Liberty's Motion for Summary Judgment. The Common Issue

<sup>34</sup> See e.g., Waste Mgmt., 137 F.3d at 45 ("[T]he company conducted no discovery on this issue during the twenty-one months in which this case was pending in the district court. Given this failure, C.B. Trucking is in no position to complain of the court's decision to examine the evidentiary sufficiency of the predatory pricing claim.").

<sup>35</sup> Dkt. No. 1425.

<sup>36</sup> See e.g., Waste Mgmt., 137 F.3d at 45 (discussing when a Rule 56(d) response would be considered "untimely").

<sup>37</sup> See Lipton Decl., ¶ 7.

<sup>38</sup> See Paterson-Leitch Co. v. Massachusetts Municipal Wholesale Elec. Co., 840 F.2d 985, 988 (1st Cir. 1988) ("The [Rule 56(d)] statement must be made, if not by affidavit, then in some authoritative manner -- say, by the party under penalty of perjury or by written representations of counsel subject to the strictures of Fed. R. Civ. P. 11 - and filed with the court.")

Discovery Order establishes that discovery over common issues is to remain open until June 2015.<sup>39</sup> Prior to the issuance of this plan, several defendants took the position that discovery was not open in this MDL and refused to participate in discovery with the PSC, which significantly impacted the PSC's ability to obtain discovery prior to the issuance of the Common Discovery Order. 40 Liberty did respond to a written subpoena early on in this litigation, but to date, Liberty has not responded to any other written discovery and no depositions have taken place, although some are scheduled for the middle of November. 41 Further, in less than 24 hours since issuing deposition notices, the PSC has already received opposition from other defendants thus demonstrating that the discovery process in this matter is just beginning and on undetermined ground.

Moreover, expert discovery has not commenced. Expert reports are particularly necessary because the construction of cleanrooms is governed by highly technical international standards set by an international governing body. 42 To fully respond to Liberty's Motion for Summary Judgment, the PSC will likely need expert testimony on how the Liberty design and construction of NECC's cleanrooms deviated from these standards and how that deviation contributed to fungal contaminants ultimately making their way into pharmaceuticals compounded by NECC in those cleanrooms, especially in light of the evidence obtained during the December 2012 inspection. Lastly, experts will be needed to explain, among other things, why the Liberty design was ill suited for placement in the NECC facility given the PSC believes the NECC building presents unreasonably high susceptibility to atmospheric pressure changes and wind patterns.

<sup>39</sup> Dkt. No. 1425 at P. 5.

<sup>40</sup> See e.g., Dkt. Nos. 595-598.

<sup>41</sup> Lipton Decl., ¶ 8.

<sup>42</sup> See generally id. at ¶ 5 and Ex. 4.

Accordingly, there is no meaningful dispute that the Plaintiffs have good cause for why they need more discovery to fully respond to the Motion for Summary Judgment and why the PSC has not yet had an opportunity to obtain that discovery.<sup>43</sup>

iii. The Lipton Declaration Establishes the Likely Existence Of Facts That Would Justify Denying The Motion For Summary Judgment.

Liberty principally seeks dismissal of the close to 100 claims against it on the factual basis that it breached no duty to the injured plaintiffs and that plaintiffs cannot prove causation. 44 The only evidence offered to support these bold conclusions is the self-serving affidavit of Jeffrey Erickson, a witness the PSC has yet to depose. It is also likely that the PSC will need to depose other key Liberty witnesses and seek necessary third party discovery if applicable based on testimony provided. It offers no independent expert proof regarding the proper design and construction of a cleanroom or how improperly constructing and/or designing construction could not lead to fungal contaminants in the compounded pharmaceuticals manufactured in that cleanroom.

As discussed above, the PSC has already uncovered evidence that Liberty's design and construction of the NECC cleanrooms did not meet necessary construction standards and that Liberty was aware that NECC was having problems with the ceiling tiles in the cleanrooms.45 Further, the PSC has already uncovered evidence that Liberty rushed the cleanrooms to certification even though it knew that certain items had not been completed and that Liberty failed to meet the construction specifications in the original contract in order to rush the cleanrooms to certification.

These are only some of the limited facts the PSC has uncovered that support its claims

<sup>43</sup> See Studentcity.com., 2013 U.S. Dist. LEXIS 173911, 4-5.

<sup>44</sup> Dkt. No. 1472 at P. 16-18.

<sup>45</sup> See discussion supra at P. 4-7.

against Liberty. More is obviously needed, and under the Court's own common discovery order, the PSC has until June of 2015 to explore the factual basis of its claims. Witnesses, especially Mr. Erickson, need to be deposed, to, at a minimum, test the sufficiency of the bold allegations contained in his affidavit.<sup>46</sup>

Based on the documents the PSC has uncovered to date and the information gleaned from the PSC's inspection in December 2012 of the NECC facility, the PSC needs additional discovery to investigate and/or prove the following:

- The ceiling tiles and grid for the 2005 and 2006 cleanrooms were defectively designed and installed which posed significant threat that contaminants could enter into the cleanrooms;
- Liberty's knowledge of the defective ceiling tiles in the 2005 and 2006 cleanrooms;
- Liberty knew or should have known that its construction and design of the cleanrooms in the NECC facility could not meet and/or continue to meet ISO standards;
- The faulty design and/or construction of the cleanrooms presented a significant risk of contamination by falling particles and the certification tests performed by Liberty failed to account for this;
- Liberty continued to work on the cleanrooms after certification and no subsequent certification testing was done to confirm the newly modified cleanrooms continued to conform to the ISO certification requirements;
- What analysis Liberty conducted prior to designing the cleanrooms and proceeding with construction;

<sup>46</sup> See e.g., Dkt. No. 1472-2 at P. 9, ¶ 18-20.

 As a result of the poorly designed and constructed cleanrooms, particular matter, including fungal spores, were able to enter the cleanroom and ultimately found their way into pharmaceuticals compounded in those cleanrooms.<sup>47</sup>

As identified earlier, the PSC has already uncovered some evidence supporting these allegations, yet more information is needed, particularly as it relates to Liberty's knowledge about the conditions of the NECC facility and cleanrooms it designed and built. Depositions are the best method for the PSC to obtain this information, but, to date, none have taken place.

Moreover, expert discovery is imperative to determine the impact that any design and construction defects had on the integrity of the cleanrooms themselves. This highly technical analysis will require detailed testimony on air flow, room pressures, air filtration systems, weather and wind patterns, and the other technical factors that go into designing and constructing a properly functioning cleanroom. 48

If established, these facts would create the existence of a genuine issue of material fact as to Liberty's breach of its duty it owed to the Plaintiffs when it undertook to design and construction a cleanroom in which it knew that pharmaceuticals would be compounded and the causal link between Liberty's actions and fungal spores ultimately being found in pharmaceuticals compounded in those cleanrooms.

Accordingly, the Plaintiffs have satisfied the remaining factors justifying Rule 56(d) relief.<sup>49</sup> The PSC maintains that discovery should continue in accordance with the Court's Common Discovery Order, and the PSC should be given the time established in this order to conduct meaningful fact discovery, and more importantly, expert discovery to fully respond to the allegations contained in Liberty's Motion for Summary Judgment.

<sup>47</sup> Lipton Decl. ¶ 9.

<sup>48</sup> See generally Lipton Decl., ¶ 5 and Ex. 4.

<sup>49</sup> See Studentcity.com, Inc., 2013 U.S. Dist. LEXIS 173911, 4-5.

## III. Conclusion

As demonstrated above, Liberty's Motion for Summary Judgment is based on facts that the Plaintiffs dispute. Plaintiffs should be given the opportunity to conduct meaningful discovery before responding to the Motion for Summary Judgment. Accordingly, under Rule 56(d)(1), the Court should deny the Motion for Summary Judgment and allow this case to proceed with full discovery before a substantive response to the motion is required.

To the extent the Court is not willing to deny the Liberty Motion for Summary Judgment outright, Plaintiffs respectfully request that the Court permit them the opportunity to brief the merits of the motion, or the lack thereof, more fully.

Dated: October 31, 2014

Respectfully submitted,

# /s/ Marc E. Lipton

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Plaintiffs' Steering Committee

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**CERTIFICATE OF SERVICE** 

I, Marc E. Lipton, hereby certify that I caused a copy of the foregoing to be filed

electronically via the Court's electronic filing system. Those attorneys who are registered with

the Court's electronic filing system may access these filings through the Court's system, and

notice of these filings will be sent to these parties by operation of the Court's electronic filing

system.

Dated: October 31, 2014

/s/ Marc E. Lipton

Marc E. Lipton

# **Certificate of Service**

**I HEREBY CERTIFY** that a true and correct copy of foregoing document was served upon the following parties by U.S. Mail on this <u>3rd</u> day of November, 2014.

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/S/ Marc E. Lipton
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